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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RUSSEL, JEFFREY E	

ART UNIT	PAPER NUMBER
1654	

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03/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,137	BERINSTEIN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,37 and 67-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,37 and 67-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. Applicant's election with traverse of the invention of Group II and the species LMDMQTFKA (SEQ ID NO:7) in the reply filed on January 7, 2009 is acknowledged. The traversal is on the ground(s) that search of all of the peptide species recited in Tables IV and V would not present an undue burden on the examiner. This is not found persuasive. The examiner counts 74 peptide species in the two tables. The examiner has not been able to discern any common (non-trivial) sequence in common with all of the peptide species, or even in common with a plurality of the peptide species, and Applicants have not pointed out any such common sequence in their response. In the absence of such a common sequence, each peptide species has to be searched individually, @ 7 databases per sequence. This constitutes an undue burden on the examiner, and on the Office.

The requirement is still deemed proper and is therefore made FINAL.

2. Included with the papers submitted on December 26, 2007 is a copy of a stamped postcard receipt for Applicants' submission on June 28, 2007. Listed on the postcard receipt are several papers which have not been scanned into the Image File Wrapper and should be considered as lost: paper copy of Sequence Listing (36 pages); marked-up copy of amended specification (80 pages); and clean copy of amended specification (77 pages). These lost papers are the basis for several objections and formality requirements set forth below. The examiner apologizes for any difficulties their loss may cause Applicants.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

A computer readable form (CRF) copy of the Sequence Listing was filed on June 28, 2007, listing 105 sequences, and was approved by STIC for matters of form. However, as noted in section 2 above, the paper copy of the Sequence Listing filed on the same date is lost. Applicants are required to submit another paper copy of the Sequence Listing (37 CFR 1.821(c) and (g)). If Applicants are going to submit a paper copy of the Sequence Listing which is identical to the Sequence Listing in the computer readable form copy filed on June 28, 2007, it is not necessary for Applicants to re-submit the CRF copy of the Sequence Listing. Regardless, Applicants must submit new statements that the paper copy and the CRF copy of the Sequence Listing are the same and contain no new matter (37 CFR 1.821(f) and (g) and 1.825(a) and (b)), and especially if the previously filed CRF copy is to be used, identifying the paper copy and the CRF copy of the Sequence Listing by the date they were filed in the Office. Correction is required.

4. An amendment to the specification appears to have been filed on June 28, 2007 - copies of this amendment were re-submitted on November 23, 2007 and on December 26, 2007. These amendments have not been entered because: (1) The page and line numbers of the amendment instructions are incorrect, probably because they are based upon the page and line numbers of the substitute specification filed June 28, 2007 which has been lost; and (2) The specification amendments are not in the form of replacement paragraphs as required by 37 CFR 1.121(b)(1)(ii).

If Applicants file a new substitute specification in response to this Office action, a separate amendment to the substitute specification should not be filed at the same time. All amendments to the specification should be included in the same amendment document,

especially in order to avoid compilation issues at the time of printing any patent which may issue based upon this application.

5. The drawings are objected to because SEQ ID NOS need to be inserted after the amino acid and nucleotide sequences recited in the drawings. See 37 CFR 1.821(d). In the alternative, and more preferably, SEQ ID NOS can be inserted into the Brief Description of these drawings occurring at page 2 of the specification. If necessary, corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The disclosure is objected to because of the following informalities: SEQ ID NOS must be inserted after all amino acid and nucleotide sequences disclosed in the specification which are subject to the sequence disclosure rules. See 37 CFR 1.821(d). Such sequences occur at, e.g., pages 14 and 30-34 of the specification. Appropriate correction is required.

7. Claims 36, 37, and 67-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear how the "derived from" and "as shown in" language in claim 36 should be interpreted. It is not clear if the claimed peptides must be exactly "as shown in" Tables IV and V, or if the "derived from" language permits further modification of the peptides. For example, it is not clear if the claim language is open-ended, e.g., embracing peptides comprising additional amino acid residues and/or modifying groups. Because the peptides designated CLP 2977 through CLP 2982 of Table V are defined at page 34, lines 5-10 as comprising an N-terminal KLH group, it is not clear if the claim embrace these peptides without any N-terminal KLH group. Similarly, in claims 67 and 70, it is not clear if the claim language should be interpreted as defining the peptides using open or closed language, i.e. it is not clear if the claims embrace peptides comprising the recited amino acid sequences plus additional amino acids and/or modifying groups. There is no antecedent basis in the claims for the phrase "the patient" at claim 37, line 2. Note that line 1 of the claim recites that a "host" is immunized.

8. Claims 37, 67, and 70-72 are objected to because of the following informalities: In claims 37, 67, and 70-72, "peptide" should be changed to "isolated peptide" so as to be consistent with the claim language of independent claim 36. At claim 70, line 1, "is" should be inserted before "selected". Appropriate correction is required.

9. Instant claims 36, 37, and 67-72 are deemed to be entitled under 35 U.S.C. 119(e) to the benefit of the filing date of provisional application 60/462,945 because the provisional application, under the test of 35 U.S.C. 112, first paragraph, discloses the claimed invention.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 36, 37, and 67-72 are rejected under 35 U.S.C. 102(b) as being anticipated by the WO Patent Application 01/47959. The WO Patent Application '959 teaches the peptides ELMLMQTFKA and SLSKILDTV, which can be included as part of an immunogenic cocktail composition. See, e.g., page 25, line 15; the paragraph bridging pages 26 and 27; and the paragraph bridging pages 28 and 29. The peptide ELMLMQTFKA is the same as Applicants' SEQ ID NO:7, except with an additional N-terminal glutamic acid residue. Note that it is unclear as to whether Applicants' claims exclude the presence of any additional amino acid residues from their claimed peptides. See the above rejection under 35 U.S.C. 112, second paragraph. The peptide SLSKILDTV is the same as that listed in Applicants' Table IV, column 1, eighth entry. Because the same active agent is being used as an immunogen in both the WO Patent Application '959 and Applicants' claims, inherently the host/patient will be immunized against the tumor antigen BFA5 in the WO Patent Application '959 to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between the WO Patent Application '959 and Applicants' claimed invention to shift the burden to Applicants to provide evidence that the claimed invention is unobviously different than the WO Patent Application '959.

12. Billing-Medel et al (U.S. Patent Application Publication 2006/0154291) is cited as art of interest, being essentially duplicative of the reference applied above. See, e.g., SEQ ID NO:28, residues 22-30, and claims 52 and 60.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
March 3, 2009